



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION IX
75 Hawthorne Street, WTR-6
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Mr. John W. Williams
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Dear Mr. Williams:

Your letter of October 12, 2009 to the US Food and Drug Administration was forwarded to USEPA Region 9 and came to my desk yesterday. My apologies for it taking so long for you to get a reply.

You bring up a good question as to the risks from ingesting arsenic in drinking water for an extended period of time. As we say in the toxicology profession, the dose is the poison. Virtually anything we ingest can be toxic if we take too much. (People can drink too much water, for example.) So I'll answer the question in two parts: what arsenic does to people and what you can expect from drinking water at the level reported for your water system. I'll also try to explain EPA's drinking water Maximum Contaminant Level (MCL) for arsenic.

With respect to arsenic, it is definitely a poison and has several adverse physiological effects. At high enough levels (about 100-200 mgs), it stops mitochondrial respiration, your cells can't generate energy, and they (and you) die. This is what is meant by acute toxicity. In addition, arsenic appears to cause oxidative damage and stimulates the formation of a variety of physiological stress-related proteins. At lower levels ingested chronically over time (1-10 mg/day), this still goes on, but not enough to kill you. Your system is merely weakened to the point that it can't fight off other kinds of cellular damage, which can build up or lead to other problems. Adverse health effects may occur only after years of exposure to these lower levels. Some of these include circulatory, neurological and liver problems.

Arsenic also has hormonal effects that can cause diseases such as diabetes. This appears to happen even at much lower levels, perhaps less than 100 ug/day. A variety of skin diseases (hyperkeratoses, blackfoot, hyperpigmentation, gangrene) are known to occur at levels starting around 100-200 ug/day (= 0.1-0.2 mg/day).

Arsenic is a known human carcinogen. It appears to cause broken and missing chromosomes and other chromosomal abnormalities. It can cause lung, bladder, and skin cancers, and may cause liver, kidney and prostate cancers. Elevated cancer levels are seen in populations drinking water

with arsenic levels of 100-200 ug/liter, which is about 200-400 ug/day. It usually takes many years of drinking water at these levels for cancers to occur. At higher levels (500-1000 ug/day), these cancers form faster.

So what does this all mean for the level of arsenic you receive (0.015-0.021 mg/liter = 15-21 ug/liter)? If you consume 2 liters of water by drinking or from cooked food, you get about 30-40 ug/day of arsenic. Medical studies don't show much if any disease at these levels. However, for all of these diseases and adverse health effects, the research suggests that arsenic is causing something to happen biochemically even at very low levels. We just can't see medical problems at these low levels. Why might that be? Most people have some physiological tolerance for arsenic. Even at high doses, not everyone dies or gets sick. Our bodies produce metallothionein (MT), a protein that can offset some of the damage caused by arsenic and other heavy metals. MT is induced by low levels of arsenic. So it may be that MT is affording enough protection that the amount of biochemical damage from low arsenic doses is dealt with by the body before something more serious occurs. This would be like the body's healing of a wound, but at the cellular level. Because individuals vary in their physiology, some may have more intrinsic protection than others. At much higher arsenic exposures, the damage might be more than MT and all other protective systems could handle, so the chance of disease would increase and be seen by the medical profession.

Finally, what does this mean with respect to EPA's MCL for arsenic, which is 10 ug/L? The Safe Drinking Water Act tells EPA to set drinking water goals at levels at or below known or anticipated adverse effects on people with an adequate margin of safety. Because of the human variation, we set our levels to protect those that might be most vulnerable to the contaminant. Our risk assessments use conservative factors to address these more-vulnerable people. For cancer-causing contaminants like arsenic, that means that our MCLs are set as low as can be practically done. (Practical means that we can actually measure it and treatment systems can remove it.) Generally, our MCLs are many times lower than any level where disease is seen by the medical profession. We want the risk level at the MCL to be so low that even if your water is somewhat above the MCL, you should be safe.

I hope that this addressed your concerns. If not, you can reach me at the above address or at 415 972-3569.

Sincerely,

Bruce A. Macler, PhD
Regional Toxicologist
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